

induced, and continues to induce, physicians and others to use the Palomar accused devices³ in a manner that infringes the method claims of Plaintiffs' Patents. Because the inducement inquiry ultimately requires analysis of how the physicians operate the Palomar devices, those physicians' records related to such uses are directly relevant to the lawsuit pending between Plaintiffs and Palomar. There is no other source from which Plaintiffs can obtain those records.

Plaintiffs issued a subpoena to Dr. Stanley Kovak in October 2007, and a revised subpoena on December 4, 2007 that is carefully and narrowly drawn to seek documents critical to the Litigation, and to avoid imposing any undue burden on Dr. Kovak. Palomar's counsel in the Litigation, Foley & Lardner ("Foley"), is representing Dr. Kovak in response to the subpoena. Although sixteen of Foley's third-party clients, including Dr. Kovak, objected and refused to produce any documents, to comply with Rule 37.2, Plaintiffs earnestly sought to avoid invoking the resources of this Court by meeting and conferring with Foley as described in Section II, *infra*. However, Foley provided a January 11, 2008 letter response that failed to respond to the issues addressed in the meet and confer and indicated that a motion to compel would be necessary, particularly with the upcoming March 10 and April 8 deadlines for expert reports and close of discovery in the Litigation. Thus, Plaintiffs respectfully request that the Court grant this motion.

³ The Palomar accused devices include the following handpieces used in combination with various Palomar systems: the Lux 1540, the Lux 1540-Z, the LuxIR, the LuxDeepIR, the LuxB, the LuxG and the LuxY.

II. FACTUAL BACKGROUND

In the Litigation, Plaintiffs⁴ accuse Palomar of inducing physicians to infringe one or more claims of the patents in suit, including by using the following Palomar handpieces in combination with various Palomar laser and other light-based systems for wrinkle treatment: the Lux 1540, the Lux 1540-Z, the LuxIR, the LuxDeepIR, the LuxB, the LuxG and the LuxY. *See* Ex. 1 (Second Amended Complaint), at ¶ 27.⁵ For purposes of the subpoena request, these are defined as the "Relevant Products." An example patent claim at issue is as follows:

1. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns and a fluence of between 10 and 150 joules per square centimeter;
directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin;
cooling an epidermal region of the skin above the targeted dermal region; and
causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.⁶

In order to gather relevant evidence of Palomar's inducement of infringement, Plaintiffs identified a number of physicians who, as evidenced by publicly available information,⁷ use or have used one or more of the infringing Palomar accused devices for wrinkle treatment and/or have functioned in a business development and marketing capacity on behalf of Palomar to demonstrate the results of wrinkle treatment with the Palomar devices. Plaintiffs issued subpoenae *duces tecum* to those physicians, including Dr. Kovak, in October 2007. Palomar's

⁴ Plaintiff Candela develops, manufactures and distributes medical and aesthetic laser and light-based technologies. Plaintiff MGH is a teaching hospital of Harvard Medical School as well as a biomedical research facility. *See* Ex. 1 (Second Amended Complaint) at ¶¶ 2-3.

⁵ All exhibits to this motion are attached to the Declaration of Craig Tolliver In Support of Plaintiffs' Motion to Compel Dr. Stanley Kovak To Produce Subpoenaed Documents.

⁶ Claim 1 of '497 Patent, Ex. 1 (Second Amended Complaint) at Ex. B.

⁷ *See* <http://www.palomarmedical.com/palomar2.aspx?pgID=1089> (Dr. Kovak providing patient photographs for use on Palomar website); http://www.miinews.com/pdf/eabg_palomar_spring07.pdf (Dr. Kovak discussing use of accused Palomar 1540 device for laser skin resurfacing).

counsel in the Litigation, Foley, contacted the majority of the physicians, including Dr. Kovak, and advised Plaintiffs that it represented them. Foley objected on their behalf, and advised that the physicians would not produce any responsive documents. In an attempt to reach agreement with the physicians, Plaintiffs subsequently withdrew those subpoenae voluntarily, reduced the number of requests and focused more narrowly on technical issues of infringement. Plaintiffs served the new set of subpoenae on the physicians on or about December 4, 2007. *See* Ex. 2 (subpoena to Dr. Stanley Kovak). The document request categories are discussed individually in Section III, *infra*.

Foley objected on behalf of the physicians, including Dr. Kovak, in nearly identical, boilerplate, objections and stated that its clients would not produce any responsive documents.⁸ *See, e.g.*, Ex. 3 (subpoena objections of Dr. Stanley Kovak). However, one physician who chose to not be represented by Palomar's counsel voluntarily produced a highly relevant set of documents under the highest level of confidentiality of the protective order, obviating the need for Plaintiffs' filing of a motion to compel for that physician's documents.

Plaintiffs promptly requested a meet and confer in order to discuss the physicians' objections and refusal to comply with the subpoena. The issues arising during that meet and confer, and Plaintiffs' attempts to compromise by proposing narrowing restrictions are summarized in correspondence from December 24, 2007, and are discussed in Section III, *infra*. *See* Ex. 4 (12/24/07 letter). During the meet and confer, Plaintiffs' counsel agreed to extend Palomar's time to respond until January 11, 2008, to conduct its inquiries and advise whether its clients would agree to voluntarily produce documents in view of Plaintiffs' attempt to reach a

⁸ The only exception is Dr. Zelickson, who committed to produce documents before being represented by Foley.

cooperative compromise, and, if so, Foley would advise as to the timing of the production. *See id.* Plaintiffs then would determine whether a motion to compel would be necessary. *See id.*

Foley's response letter fails to address what the parties discussed on December 21 and does not state whether any physician (with the one exception noted above) will produce any document in response to any document category, and instead generally asserts once again that its clients would encounter "undue burden" if they were to search for documents. *See* Ex. 5 (1/11/08 Letter). This continuing pattern of delay and obfuscation necessitated the filing of this motion.

III. DISCUSSION

A. **Plaintiffs' Document Request Categories Are Narrowly Drawn To Seek Information That Is Necessary To The Litigation And To Minimize Any Burden On The Physicians**

Plaintiffs allege, *inter alia*, that Palomar has induced its customers, such as physicians, to infringe the Plaintiffs' patents. Thus, the physicians' uses of the Palomar accused products are directly relevant to the Litigation. *See Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1364 (Fed. Cir. 2004) ("The jury found LabCorp liable for indirect infringement. The record must show the presence of direct infringement . . . Thus, this court must examine whether there is substantial evidence in the record of the physicians' direct infringement."). The document request categories included in the subpoena *duces tecum* to Dr. Kovak are narrowly drawn to seek relevant information, as discussed below.

Category 1: All documents referring to this Litigation, drafted as a result of this Litigation, or provided to Palomar or some other person as a result of this Litigation.

Any documents that relate directly to the Litigation would be relevant because those documents are reasonably calculated to lead to admissible evidence of Dr. Kovak's intentional actions in response to the Plaintiffs' patent claims, and the nature and extent of direct infringement by Dr. Kovak and other physicians. Moreover, such documents are likely to reveal

Palomar's interactions with the physicians and therefore would also be probative of the manner by which Palomar induced infringement. *See, e.g.*, 35 U.S.C. § 271(c) (requiring the patent infringer to "actively induce[] infringement"). This particular document category is targeted specifically towards communications relating to the Litigation, and thus is narrowly drawn. There is no reason that Dr. Kovak cannot produce his documents relating to the Litigation.

During the December 21 teleconference, Foley admitted that one or more of its physician clients "possibly" could have documents responsive to this category but did not know who might have such documents, although Foley speculated that such person probably would not have many such documents. *See Ex. 4* (12/24/07 Letter). Foley's January 11 letter adds that Foley understands that its physician clients have "no responsive documents," yet then states that it will "confirm whether any exist" at some unspecified time. *See Ex. 5* (1/11/08 Letter).

In an effort to minimize any burden on Dr. Kovak, Plaintiffs proposed during the meet and confer to limit the date range of this category to the time period spanning from December 19, 2006, the time this lawsuit was filed, up until the time that Foley represented Dr. Kovak for purposes of the document subpoena, so that Dr. Kovak would not need to create a privilege log for any communications with Foley.

Category 2: All documents concerning Recipient's marketing of the Relevant Products for Wrinkle Treatments to actual or potential Patients, including without limitation copies of each draft or final version of Recipient's website and each brochure, pamphlet, flyer, mailer, CD-ROM, photograph or other image, PowerPoint presentation or article that was actually presented to or viewed by an actual or potential Patient, or available for presentation to or viewing by an actual or potential Patient, communications with any marketing consultant or firm regarding the same, or communications with Palomar regarding the same.

Category 3: All documents concerning any communication between Recipient and either (i) Palomar, (ii) a Palomar Doctor, (iii) a Relevant Product owner who is known to Recipient, (iv) a Relevant Product potential purchaser who is known to Recipient, or (v) any person providing clinical training, where such communication is concerning the use, operation, sales, or marketing of a Relevant Product to perform a Wrinkle Treatment.

Method claims of the Plaintiffs' patents-in-suit refer to "[a] method for treating a wrinkle in human skin," and thereafter recite a limitation reciting "causing thermal injury . . . to elicit a healing response that produces substantially unwrinkled skin." *See, e.g.*, '497 Patent, claim 1.

The documents in Categories 2 and 3 are therefore relevant because a physician's marketing of the accused products for wrinkle treatment is probative evidence of how the devices are used in practice and of the nature and extent of the infringing use for wrinkle treatment; and thus relevant to direct infringement and damages. Moreover, such documentation is also probative of how Palomar instructs that the devices may be used, and would be relevant to the inducement issue. *See, e.g.*, 35 U.S.C. § 271(c).

During the December 21 meet and confer, Foley advised that its physician clients were confused by the phrase in Category 2 calling for marketing documents that were "actually presented to or viewed by an actual or potential Patient" because they could not tell whether any document had actually been shown to a patient. Accordingly, Plaintiffs agreed to remove that clause in order to relieve the physicians' concern. Plaintiffs also agreed to limit the date range of this category to the time period subsequent to and including January 1, 2006, in order to minimize any burden on the physicians. There is no reason Dr. Van Dam should not produce the highly relevant documents falling within categories 2 and 3.

Category 4: Documents showing the number of times Recipient, or any other person in Recipient's office or practice, has used the Relevant Product for any Wrinkle Treatment.

Documents falling within this category relate directly to the manner in which the Palomar accused products are used to practice the method claims of Plaintiffs' Patents, including the nature and extent of that use. Dr. Kovak's primary concern with this request appears to relate to his manner of maintaining documents. That concern is addressed below in Section III(B).

Category 5: All documents concerning any evaluation of whether a Wrinkle Treatment with a Relevant Product has (i) reduced a wrinkle, fine line, rhytid, or rhytide in any way,

(ii) improved skin tone or texture in any way, (iii) decreased laxity of the skin in any way; or (iv) achieved skin tightening in any way, including, but not limited to, measurements, evaluation of photographs or other images, statistical analyses, data summaries, any patient treatment form (including without limitation, patient progress reports, operative reports and progress or follow-up reports) or any feedback or self-evaluation from any Patient receiving a Wrinkle Treatment.

Category 6: All before and after photographs or other images which were (i) provided to any of Palomar, a Palomar Doctor, a Patient or potential Patient, or a Customer or potential Customer; (ii) used by Recipient in any public presentation or publication; (iii) given by Recipient to any other person for use or potential use in any public presentation or publication; (iv) posted on the Lux Club website; or (v) used in any advertising materials by or on behalf of Recipient, wherein such photographs or images are depicting a person who has been treated with one or more of the Lux 1540, Lux 1540-Z, Lux IR, or Lux DeepIR for Wrinkle Treatment, and all communications with Palomar or with any person concerning any such photographs or other images, including, but not limited to, Patient consent forms.

Categories 5 and 6 relate to evaluations of whether a Palomar accused device has been used to treat wrinkles, and/or the extent to which it has been so used. These categories are particularly relevant because Palomar has argued that the patent claim phrase "that produces substantially unwrinkled skin" requires a particular level of wrinkle reduction. *See* Ex. 7 (excerpt from Palomar claim construction brief) (arguing that "substantially unwrinkled skin" should be construed to mean "removes substantially all of the wrinkle to produce smooth skin"). Documents responsive to these categories would relate to the level of wrinkle reduction performed by Palomar's accused devices.⁹

During the December 21 meet and confer, Plaintiffs again sought to ensure that the physicians' burden would be minimized as much as possible. *See* Ex. 4 (12/24/07 Letter). First, Plaintiffs emphasized that these categories do not call for raw photographs but instead seek "evaluation[s]," and therefore encompass such items as a numerical estimate as to the amount of wrinkle reduction shown, a written assessment or description of wrinkle reduction, or feedback from a patient. *See id.* Second, Plaintiffs again agreed to limit the date range of this document

⁹ Category 7 was withdrawn.

category to the time period subsequent to and including January 1, 2006. *See id.* Dr. Van Dam should produce these probative, responsive documents.

Category 8: All documents concerning the generation of any Wrinkle Treatment data for actual or potential submission to the FDA, including but not limited to, (i) all clinical study protocols for Wrinkle Treatment with a Relevant Product; (ii) all Wrinkle Treatments made pursuant to IDE G050009 or any other Investigative Device Exemption (IDE) for a Relevant Product (including without limitation all settings used on Relevant Products), (iii) all documents concerning any clinical study, clinical treatment or clinical data concerning the use of a Relevant Product for Wrinkle Treatment that is part of a study that is subject to review by an IRB or institutional ethics committee; (iv) all data and analyses (including raw data, photographs or other images, compilations, summaries or statistical analyses) generated pursuant to IDE G050009 or any other Investigative Device Exemption (IDE) for Wrinkle Treatment with a Relevant Product, (v) all documents concerning Palomar's intent or desire to get FDA clearance for use of a Relevant Product for any Wrinkle Treatment (or status or progress in gaining any such FDA clearance); and (vi) all documents concerning any draft or final 510(k) for the Lux IR, the Lux DeepIR, the Lux 1540 or the Lux 1540-z and concerning any aspect of Wrinkle Treatment.

Medical devices, including the Palomar accused devices, and their applications are regulated by the FDA. This category seeks documents concerning any involvement by Dr. Kovak in Palomar's process of soliciting, selecting, evaluating and submitting clinical data to the FDA for the accused devices and their use for wrinkle treatment. Any such documents should be maintained in separate files by Dr. Kovak and should be readily available for production. Such documents also would be highly relevant because the documents likely would describe the specifics of how the Palomar accused devices are used by Dr. Kovak, and by the aesthetic medical industry in general, for wrinkle reduction and the biological responses related to their uses.

In his objections, Dr. Kovak does not state that he lacks FDA documents, but instead raises boilerplate objections, as with the other document categories. *See Ex. 3* (Dr. Stanley Kovak's subpoena objections). Dr. Kovak should thus produce the responsive documents.

Category 9: All documents concerning feedback from Recipient's Patients regarding any Wrinkle Treatment using one or more of the Relevant Products, including, but not limited to, documents concerning any feedback regarding the results of such treatment or procedure.

As already discussed with respect to Categories 5 and 6 above, Palomar has raised issues concerning the level of wrinkle reduction required by Plaintiffs' Patents. This document category, which seeks patient feedback regarding wrinkle reduction, including the results, relates to that issue. Moreover, it is common for defendants in patent cases to argue that the patented invention is unsuccessful. The documents sought by this category also pertain to that issue.

During the December 21 meet and confer, Plaintiffs again agreed to limit the date range of this document category to the time period subsequent to and including January 1, 2006, so as to relieve the burden on the subpoenaed physicians. *See* Ex. 4 (12/24/07 Letter). Dr. Kovak should not be permitted to continue to withhold responsive documents.

Category 10: All documents concerning Marketing/Seminar Materials, Lux Club Materials, Sponsored Events, Training Materials or Treatment Plans, including, but not limited to, who creates or pays for any of the foregoing Marketing/Seminar Materials, Lux Club Materials, Sponsored Events, Training Materials or Treatment Plans.

During the December 21 meet and confer, Plaintiffs advised that this category may be considered to be specific examples of the types of documents called for by Categories 2 and 3, discussed above. *See* Ex. 4 (12/24/07 Letter). As a result, the documents sought by this Category have been discussed above.

B. Dr. Kovak Would Not Be Unduly Burdened By Responding To The Subpoena

1. Dr. Kovak's subpoena objections do not establish "undue burden"

Whether a subpoena imposes an "undue burden" depends upon "such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed." *See Bridgeport Music, Inc. v. UMG Recordings, Inc.*, 2007 WL 4410405, *2 (S.D.N.Y. Dec. 17, 2007), *citing Travelers Indemnity co. v. Metropolitan Life Ins. Co.*, 228

F.R.D. 111, 113 (D. Conn. 2005). The party opposing the subpoena bears the burden of demonstrating that compliance with the subpoena would be unduly burdensome. *See id.* at *1.

The documents sought by Plaintiffs are relevant to the Litigation and are largely unavailable from other sources, as previously discussed. In addition, the requested documents are precisely described and the relevant categories are restricted to the time period of January 1, 2006 and later, pursuant to the parties' December 21 meet and confer. *See* Section III(A), *supra*. Moreover, Dr. Kovak's subpoena objections simply recite a litany of boilerplate objections but do not provide any particular detail of an alleged undue burden that would be suffered by Dr. Kovak in responding to the subpoena. *See* Ex. 3 (Dr. Stanley Kovak's subpoena objections). During the December 21 teleconference and in its January 11 letter, Foley referred generally to burden that may be experienced by its seventeen third-party physician clients, but was unable to discuss anything that would allow Plaintiffs to assess Dr. Kovak's situation on a particularized basis.

2. Dr. Kovak should be able to locate responsive documents in his files

During the December 21 meet and confer, Foley advised that the primary concern on the part of certain of its seventeen third-party physicians was the manner in which they maintained their records. *See* Ex. 4 (12/24/07 Letter). This is because one or more of Foley's clients allegedly did not have any mechanism to determine what Palomar accused device (or any other device) the physicians may have used with any patient, or how many times total the physicians had used a Palomar device, short of reviewing each patient file individually. *See id.* Foley stated during the meet and confer that "some" of its physician clients stated that they did not bill according to treatment performed or product/device used. *See id.* However, Foley was unable to identify which clients said that, and did not know whether the other clients (i.e., other than the

"some") stated that they did bill according to treatment performed or produce/device used, or whether they had not been asked the question. *See id.*

In light of the foregoing, Plaintiffs have no reason to believe that Dr. Kovak is unable to determine which of his patients were treated with the Palomar accused devices for purposes of wrinkle treatment. In an attempt to reach a cooperative compromise, however, Plaintiffs agreed to limit most of the document request categories to the time period subsequent to and including January 1, 2006, as discussed in Section III(A), *supra*.¹⁰ Any document category that arguably involves searching of patient records should now involve only a two-year timespan.

3. **Dr. Kovak's confusion regarding the phrase "wrinkle treatment" does not excuse the failure to produce documents**

Plaintiffs used the phrase "wrinkle treatment" to limit the document request categories, so that the categories would not be directed broadly to the physicians' use of the Palomar accused devices but only to wrinkle treatment. During the December 21 meet and confer, Foley stated that certain of its physician clients could not determine whether certain uses of the Palomar accused devices would constitute "wrinkle treatment[s]," despite the definition in the subpoena, and thus were confused by the document categories, although Foley did not advise which physicians had this concern. *See Ex. 4 (12/24/07 Letter).*

Even if this concern is shared by Dr. Kovak, it is not a sufficient reason for a wholesale refusal to produce any documents whatsoever. If there is any particular treatment that, in Dr. Kovak's estimation, *may* be a "wrinkle treatment" but Dr. Kovak is somehow confused about whether it for sure qualifies as "wrinkle treatment," then Dr. Kovak can produce those documents and allow the parties to make that determination. At the very least, if Dr. Kovak

¹⁰ Plaintiffs made this compromise despite the fact that their earliest patent-in-suit, the '801 Patent, issued in 1998.

insists on withholding such documents, then he should advise Plaintiffs' counsel of that fact but should nevertheless produce the other documents that are clearly responsive. The bottom line is that Dr. Kovak should not decline to produce any documents whatsoever based on an alleged confusion concerning the term "wrinkle treatment."¹¹

4. HIPAA

Dr. Kovak's subpoena objection states that the protective order in this lawsuit is "insufficient" to protect medical records or patient information in view of the Health Insurance Portability and Accountability Act ("HIPAA"). However, the Protective Order entered in this case fully complies with the requirements of HIPAA and gives Dr. Kovak all necessary protection.¹² See *EEOC v. Boston Market*, 2004 U.S. Dist. LEXIS 27338, *8, 14-15 (E.D.N.Y. 2004) (HIPAA "allows disclosure of health information without patient consent . . . in response to a subpoena or discovery request if the health care provider receives adequate assurance that . . . reasonable efforts have been made to secure a protective order."); *id.* at * 15 (protective order must "prohibit the parties from using or disclosing the protected health information for any purpose other than the litigation" and "must require the return or destruction of the protected health information" following the litigation).¹³

¹¹ Alternatively, Plaintiffs advised during the December 21 meet and confer that the physicians could remove the "wrinkle treatment" limitation altogether or propose an alternate definition of "wrinkle treatment," if that alleviated their alleged concern. See Ex. 4 (12/24/07 Letter).

¹² See Ex. 2 (subpoena to Dr. Kovak) at Attachment 1 (Amended Protective Order ¶¶ 3, 7, 11 (restricting use of confidential materials), ¶ 24, (requiring return or destruction of materials).

¹³ Because of the existence of the protective order, Dr. Kovak need not redact information from his records. Nothing in the Act requires *both* redaction *and* a subpoena accompanied by a qualified protective order. However, Plaintiffs do not object if Dr. Kovak chooses to redact his patient records prior to production for patient identifying information, such as social security number or name.

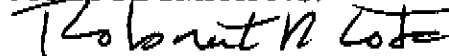
IV. CONCLUSION

For the reasons set forth herein, Plaintiffs respectfully request that this Court grant Plaintiffs' Motion for an Order to Compel and order Dr. Stanley Kovak to permit production, inspection and copying of the subpoenaed documents for Categories 1-6, and 8-10 of the subpoena *duces tecum*.

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Respectfully submitted,

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